IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

U.S. ex rel. SCHUMANN	:	CIVIL ACTION
	:	
v.	:	
	:	
ASTRAZENECA PHARMACEUTICALS LP, et al.	:	NO. 03-CV-5423

MEMORANDUM AND ORDER

Ditter, J. January 25, 2013

In this whistleblower's complaint it is alleged that defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AZ") violated federal and state false claims statutes by entering into fraudulent agreements to sell its brand-name drugs.[1] AZ has filed this motion to dismiss the complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). For the reasons set forth below, I will grant AZ's motion and dismiss the relator's complaint.

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[1] In addition to the state claims, the relator raises four violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729, against AZ. In Count V, he claims AZ "knowingly presented and caused to be presented to the Government false or fraudulent claims for payment," in violation of § 3729(a)(1). *Fourth Am. Compl.* ¶ 257. Count VI alleges AZ "knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, thereby causing false or fraudulent claims for payment to actually be made," in violation of § 3729(a)(2). *Id.* ¶ 260. Count VII raises a claim that AZ "knowingly conspired with Medco and others to commit acts in violation of 31 U.S.C. § 3729(a)(1) & (a)(2)," and that AZ and Medco "committed overt acts in furtherance of the conspiracy. *Id.* ¶ 263. Finally, in Count VIII it is alleged that AZ "knowingly avoided or decreased its obligations to pay or transmit money to the government. Specifically, [AZ]: (1) made, used, or caused to be made or used, a record or statement to conceal, avoid, or decrease an obligation to the United States; (2) the records or statements were in fact false; and (3) they knew that the records or statements were false," in violation of § 3729(a)(7). *Id.* ¶ 266. Although raised as separate counts, the violations raised are interrelated and supported by the same factual assertions.

The relator raised these same four claims against defendants E.I. du Pont de Nemours and Company, DuPont Pharmaceuticals Company, and Bristol-Meyers Squibb Company (collectively "BMS") in Counts I through IV of this complaint. I previously granted a Rule 12(b)(1) motion filed by BMS. *See United States ex rel. Schumann v. AstraZeneca, et al.*, 2010 U.S. Dist. LEXIS 109519 (E.D. Pa. Oct. 13, 2010). In that decision, I also found that the relator had sufficiently pleaded a claim against AZ pursuant to Rule 12(b)(6). AZ had deferred filing this motion under Rule 12(b)(1) contesting jurisdiction until I ruled on its Rule 12(b)(6) motion.

I. FACTS

This motion concerns many of the same facts as set forth in my October 13, 2010 opinion. The relator, Karl Schumann, is a registered pharmacist and was the vice-president of pharmaceutical contracting for Medco from December 1999 to January 2003. It is in this capacity that the relator contends he learned the information set forth in this *qui tam* action – that AZ paid disguised, undisclosed rebates, fees, and grants to Medco, a purchaser of its products, Prilosec and Nexium.

Medco has been one of the largest pharmacy-benefit managers ("PBM") and mail-order pharmacies in the country. "Medco provides services to health plans, including formulary[2] management, the development of pharmacy networks, negotiation of drug rebates with manufacturers, generic substitution, mail service pharmacies, and drug utilization review programs." *Fourth Am. Compl.* ¶ 33. Contracting with Medco was "attractive to health plans because of the potential to contain escalating pharmacy costs through rebates and other discounts." *Id.* Medco negotiated with drug manufacturers and retail pharmacies to obtain discounts on prescription drugs for its health plans and had considerable leverage with drug manufacturers in deciding which of their drug products were dispensed in their retail pharmacy networks and mail-order pharmacies. In other words, Medco acts "as a middleman between governmental entities that pay for

[2] A formulary is a list of drugs that Medco customers agree to purchase under their drug benefit program. Medco also selects drugs to be included in its Preferred Prescriptions Formulary ("PPF") based on the manufacturer's rebates. *Fourth Am. Compl.* ¶ 130. Inclusion in the PPF ensured higher sales. *Id.* ¶ 131.

prescription drugs." *Id.* ¶ 129.

AZ manufactures, markets, and sells drug products in Pennsylvania and throughout the United States. Prilosec and Nexium are brand-name drugs manufactured by AZ.[3] Relator contends that "AZ knew that Medco played a critical role in increasing prescription drug sales to governmental entities and other private payers." *Id.* This influence was evidenced in the "promulgation of drug 'formularies' for Medco's managed care customers." *Id.* ¶ 130.

Under certain federal laws, drug manufacturers who participate in government programs, such as Medicaid or 340B, must pay rebates to the government, so that the government will not pay more for drug purchases than the best price for which the manufacturer sells the drug to other purchasers. Relator contends that AZ entered into sham contracts with Medco to induce it to purchase and dispense to government plan patients its brand-name drugs, rather than the equivalent generic drugs, in violation of anti-kickback laws,[4] causing false reports and false claims for reimbursement of those drugs to be submitted to government plans. He alleges that AZ submitted false best price

[3] Prilosec and Nexium provide long-lasting gastric acid reduction, and are classified as "Proton Pump Inhibitors" or PPIs.

[4] The federal Anti-Kickback Act ("AKA") is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business. *See* 42 U.S.C. § 1320a-7b. Although the AKA does not afford a private right of action, the FCA provides a vehicle whereby individuals may bring *qui tam* actions alleging violations of the AKA. *See* 31 U.S.C. §§ 3729–3733. Thus, there is not a separate count alleging a violation of the AKA, but these allegations form the basis for alleging a conspiracy to violate the FCA.

reports for the defendants' brand-name drugs, causing false claims for rebates of Medicaid and 340B expenditures to be submitted to the government. The alleged sham contracts between AZ and Medco included rebates, service fees, disease-management fees, and unrestricted educational grants from 1996 through 2003 related to the drugs Prilosec and Nexium. Relator contends that this scheme permitted AZ to hide the lower, actual cost of these drugs from the government, and as a result, the government overpaid for them. The claims against AZ are identical, with the exception of the specific drugs involved (here, Prilosec and Nexium) to the claims against BMS (that involved Coumadin).

In this motion to dismiss, AZ contends that Relator's allegations were already publicly disclosed in the same complaints I cited in granting BMS's motion to dismiss, and that Relator does not qualify as an original source. Thus, the same jurisdictional defects would require dismissal of the claims against AZ.

Relator asserts that the schemes revealed in the complaint against AZ are fundamentally different than any publicly disclosed claims because of the added influence of two managed care plans. As described by the relator, AZ used schemes to "launder discounts through Medco to be provided to select, large managed care plans who would agree to add Nexium [and Prilosec] to their formularies." *Id.* ¶ 173-74. As part of the negotiations between Medco and AZ, Medco made clear that AZ would have to permit Medco to pass rebates on "to certain of its important customers (*i.e.*, so-called trophy

accounts) who insisted on pricing for these drugs equal to the cheapest drug in the PPI category, at the time Protonix." *Id.* ¶ 174. Although identified in the amended complaint as Managed Care Plan A and Managed Care Plan B, the briefs in relation to this motion have identified these managed care plans as Highmark Blue Cross Blue Shield and United Health Group. These deals provided steep discounts to Highmark and United that would not be reported as setting a new best price on those drugs.

According to Relator, his responsibilities with Medco included working directly with Highmark and United. He contends these two managed care groups were large accounts, and thus, unlike other Medco accounts, they were actively involved in the negotiation of rebates and other deals – they did not simply accept the deals negotiated by Medco on behalf of other customers. Moreover, because of the size of Highmark and United, it was important to AZ that Prilosec and Nexium remain on their formularies. Relator contends Highmark and United used this leverage to negotiate additional discounts, however, all rebates were paid to Medco and Medco passed the savings on to clients with contracts that required Medco to do so.

Relator describes these "Special Deals" as follows:

- Cost Equalization Pricing. AZ provided monies through Medco to "trophy accounts" (Highmark and United among others) which would match the pricing of the cheapest branded PPI on the market. *Id.* ¶¶ 174-76. These discounts were only available to plans that included Nexium in their formularies and only for as long as Medco had an agreement with AZ. *Id.* ¶ 182.

- DHS Program Disease Management Agreement. AZ offered free Digestive Health Services ("DHS") funded by AZ. Relator contends that, under the terms of the

agreement, AZ paid Medco $60 million over four years – not for any bona fide services but for Medco's ability to increase the market share of Prilosec and ensure it would remain a preferred PPI. *Id.* ¶¶ 136-38. This program was later amended to cover Nexium. *Id.* ¶¶ 143-46. Relator asserts that few patients enrolled in these services and Medco was unable to "capture the data needed to prove this program had any value." *Id.* ¶¶ 140, 147-48.

- RationalMed Program. Medco offered free RationalMed services funded by AZ. RationalMed is a Medco program that profiles physicians' prescribing habits, examines potential adverse reactions between drugs and notifies physicians of potential adverse reactions and alternate drugs that could be used. *Id.* ¶ 223. AZ paid Medco $200,000 to subsidize this program in exchange for the promise to help retain Nexium's market share by not adding a competing drug to a trophy account's formulary. *Id.* ¶¶ 224-28.

- Customer Capability Agreement. Medco offered a free formulary mailing funded by AZ. Under this agreement, AZ paid $1,000,000 to Medco for mailings for physicians and pharmacies, telephone promotions, and a coupon program to promote the sale of Prilosec. *Id.* ¶¶ 217-20.

- Brand for Generic Mail Pharmacy Program. In anticipation of the patent expiration for Prilosec, AZ agreed to bill Highmark and United at the price of the generic version of Prilosec if they dispensed Prilosec in place of the generic drug in their mail service pharmacies. *Id.* ¶ 186.

These agreements, or "kickbacks," were designed to induce Medco customers, including Highmark and United, to continue dispensing Prilosec, and later Nexium,[5] rather than any other less expensive generic drug. Relator asserts that he learned of these "fraudulent schemes to maintain market dominance for Prilosec and Nexium" through his duties at Medco and "his direct participation in the negotiation of these agreements."

[5] AZ lost patent exclusivity for Prilosec in October 2002. In anticipation of that loss of exclusivity and increased competition from other PPIs and generic versions of Prilosec, AZ developed a new PPI, Nexium. Relator asserts that the success of Nexium was "contingent on . . . getting Nexium adopted by Medco and its large managed care plan customers like Highmark and United." *Relator's Mem*., 3.

Relator's Mem., 6. Moreover, by using these deals, AZ was able to keep its market advantage and hide the fact that Medco was able to obtain Prilosec and Nexium for its customers at a lower price than the government in violation of the best price program.

II. DISCUSSION

Relator filed this *qui tam* action under federal and state statutes that allow private persons with knowledge of past or present fraud against the government to bring claims on its behalf. 31 U.S.C. § 3730. AZ asks that I apply the same subject matter jurisdictional bar to the claims against it as to those asserted against BMS.[6] The relator argues that his complaint describes schemes that are not limited to AZ and Medco, but include Highmark and United, and therefore, are "fundamentally different from any purported public disclosure the AstraZeneca Defendants claim would have set the Government on the trail of their fraud." *Relator's Mem.*, 1.

A. Public Disclosure Bar

AZ asserts that the relator's allegations were disclosed in publicly filed complaints, government investigations, and media reports, and he is not an original source. As a result, this complaint must be dismissed.

As I explained in my earlier opinion, the FCA public disclosure bar is designed to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits" based on information already know to the government. *Graham Cnty.*

[6] Before addressing the merits of a case, I must resolve any jurisdictional challenges. This challenge is to subject matter jurisdiction pursuant to 31 U.S.C. § 3732(a).

Soil & Water Conservation Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1407 (2010). The public disclosure bar divests a court of subject matter jurisdiction in *qui tam* actions where:

> (1) there was a 'public disclosure;' (2) 'in a criminal, civil, or administrative hearing, in a congressional, administrative or [GAO] report, hearing, audit, or investigation, or from the news media;' (3) of 'allegations or transactions' of the fraud; (4) that the relator's action was 'based upon;' and (5) the relator was not an 'original source' of the information.

United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 332 (3d Cir. 2005) (quoting 31 U.S.C. § 3730 (e)(4)(A)).

> A "qui tam action is 'based upon' a qualifying disclosure if the disclosure sets out *either* the allegations advanced in the qui tam action *or* all of the essential elements of the qui tam action's claims." *United States ex rel. Mistick PBT v. Hous. Auth. Of City of Pittsburgh*, 186 F.3d 376, 388 (3d Cir. 1999) (emphasis added). "To be 'based upon' the publicly revealed allegations or transactions," the allegations in the relator's complaint need not be "actually derived from" the publicly disclosed allegations. *United States ex rel. Atkinson v. Pa Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007).[7] Rather, they "need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Id.* Substantial similarity exists where there is "substantial identity" between the publicly disclosed allegations and the allegations in the relator's complaint. *United States ex rel. Poteet v. Medtronic,*

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[7] In *Atkinson*, the Third Circuit used a formula to determine the amount of information necessary to trigger the public disclosure bar:

> If X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements . . . [I]f either Z (fraud) or both X (misrepresented facts) and Y (true facts) are disclosed by way of a listed source, then a relator is barred from bringing suit under § 3730(e)(4)(A) unless he is an original source.

Atkinson, 573 F.3d at 519.

Inc., 552 F.3d 503, 514 (6th Cir. 2009).

United States ex rel. Feldstein v. Organon, Inc., 364 Fed. Appx. 738, 741 (3d Cir. 2010).

AZ offers a number of public disclosures it contends the relator's claims are "based upon." For the reasons discussed below and as set forth in my previous opinion addressing the relator's allegations against BMS, I conclude that his allegations against AZ are based upon previously disclosed allegations and transactions because they are supported by and substantially similar to allegations already publicly disclosed when he filed his complaint.

1. FCA Violations Based on Kickback Claims Against AZ

The essential elements of the kickback scheme are that AZ concealed the true nature of rebates that were meant to induce Medco to favor Prilosec and Nexium over equivalent but less expensive generic drugs, and at the same time conceal the real price Medco customers were paying for these drugs. In furtherance of this conspiracy, AZ filed various reports and requests for reimbursements that were fraudulent because they did not reflect the true cost of these drugs. AZ has presented numerous instances where facts describing this same type of scheme had been publicly disclosed – prior to Relator's disclosure to the government in September 2003. As discussed with regard to BMS, the question is whether these disclosures were sufficient to put the government on notice of AZ's fraud.

They were. For example, a class action suit filed in July 2003 alleged that AZ,

along with BMS and other drug manufacturers, "conspired with Medco and other pharmacy benefit managers 'to collect inflated prescription drug payments' by providing 'rebates, hidden price discounts and/or other unlawful financial inducements' to encourage the use of their products." *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456, C.A. No. 01-12257 (D. Mass July 28, 2003) (AZ Mot. to Dismiss, Exh. 1). The complaint specifically alleged that AZ "engaged in an ongoing deliberate scheme to inflate AWP"[8] for Nexium and Prilosec, among other drugs. *Id.* ¶ 231. The consolidated complaint goes on to allege that PBMs, including Medco, "are now turning to drug manufacturers for hidden profit-making schemes, because PBM clients are no longer allowing PBMs to collect as much for claims administration. *Id.* ¶ 654. Thus, AZ and Medco "engaged in hidden profit-making schemes" of three types: 1) "garnering rebates and other 'soft dollars' from drug manufacturers . . . without disclosing to their health plans the true amounts of the rebates;" 2) "pocketing secret spreads between actual drug costs and the prices charged to health plans"; and 3) "keeping secret discounts provided by drug manufacturers in association with the PBM's mail order operations." *Id.*

It was further alleged that as a result of their reliance on the manufacturers, PBMs took instructions and commands from the manufacturers regarding the use of AWP, not only so that they could keep part of the spread, but also so as to continue to earn from the manufacturers: (i) *Access rebates* for placement of products on the PBMs' formulary; (ii)

[8] AWP denotes average wholesale prices.

Market share rebates for garnering higher market share than established targets; (iii) *Administrative fees* for assembling data to verify market share results; and (iv) *Other fees and grants* in an effort to promote products. *Id.* ¶ 657. These allegations mirror those of the relator's in this action.

Other cases involved substantially similar kickback allegations. *See, e.g., State of W. Va. ex rel. Darrell v. McGraw, Jr., Attorney Gen. v. Medco Health Solutions, Inc.*, No. 02-CV-2944 (Circuit Court of Kanawha County, W. Va. filed Nov. 13, 2002) (complaint alleged that Medco "obtained compensation" including rebates, discounts and other fees from drug manufacturers "in exchange for Medco's discretionary decisions to provide access to, or to favor specific drugs on, Medco's standardized formulary, or to favor specific drugs in Medco's drug switching programs," and that "Medco often decided to favor higher-cost drugs over lower-cost therapeutic equivalents in exchange for the receipt of manufacturer rebates that Medco retained for itself."); *Allard's Bell Park Pharmacy, Inc. v. Abbott Labs.*, No. 02-CV-4002, Am. Compl., ¶¶ 110, 116-117 (E.D.N.Y. filed July 15, 2002) (allegations against AZ predecessor and manufacturer of Prilosec that it violated the anti-kickback laws by excluding generic manufacturers and promoted its own drugs "at a contracted discount or with respect to which the [mail-order pharmacy] will be paid a rebate, bribe or kickback").[9]

[9] As I discussed in the BMS decision, these cases are only some examples of relevant public disclosures and the exhibits include additional cases provided by the defendants that show how Medco used sham contracts that required the drug manufacturers to "pay kickbacks in the form of rebates, discounts and other soft dollars . . . in exchange for Medco's discretionary decisions to provide access to, or to favor specific drugs on [] Medco's standard formulary, and those incentives were not disclosed." *See Schumann*, 2010 U.S. Dist. LEXIS 109519, at *15.

In addition, the media reported allegations that Medco hid drug company rebates by listing them as data fees, management fees, and administration fees. Numerous articles specifically discussed how Nexium and Prilosec were promoted over generic alternatives through the use of allegedly secret payments, discounts and rebates. *See, e.g., A System to Save on Drugs Falters*, PHILADELPHIA INQUIRER, Feb.10, 2003; *When Success Sours: PBMs Under Scrutiny*, MANAGED CARE MAG., Sept. 2002; *Two Hats: Firms Paid to Trim Drug Costs Also Toil For Drug Makers*, WALL ST. J., Aug. 14, 2002.

Relator contends that his complaint "contains materially different transactions and allegations, which are undisclosed in any of the sources borrowed by the [AZ] Defendants." *Relator's Mem.*, 7. Relator argues that his claims against AZ are different because he has expanded the fraud claims to include Highmark and United. He argues that to qualify as public disclosures, the prior complaints would have had to show that (1) AZ entered into special deals specifically with Highmark and United to prefer Prilosec and Nexium; (2) the deals were structured as kickbacks and meant to evade best price reporting; (3) the deals defrauded the government.

I find this to be a distinction without consequence[10] because the "material transactions giving rise to the alleged fraud were already disclosed in the public domain." *United States ex rel. Feldstein v. Organon, Inc.*, 264 Fed. Appx. 738, 743 (3d Cir. 2010). According to the complaint, any benefit resulting from the alleged schemes to Highmark

[10] A change of watch aboard ship does not mean it will change its course, speed, or objective.

and United was dependant on Medco and its contracts with AZ and all monies were "laundered" through Medco. *Fourth Am. Compl.* ¶¶ 182-83. The nature of the fraud was not changed with the addition of two more named participants or because Medco dod not retain all rebates (or profits from the fraud) for itself. Moreover, it is AZ that is alleged to have violated the FCA and those violations are not changed by the participation of Highmark and United in contract negotiations. Thus, as in this case, where the fundamental allegations of misconduct are substantially similar to prior disclosures, the naming of an additional entity engaged in substantially the same conduct, or which was able to benefit as the result of Medco's conduct, does not change the nature of the publicly disclosed fraud – that is AZ's filing of false or fraudulent rebate reports and reporting false and fraudulent best prices.

Moreover, it was publicly disclosed that Medco was passing the AZ rebates on to at least some of its health plan clients and that the government was aware of it. For example, one article in U.S. NEWS & WORLD REPORT, *When is a Rebate a Kickback?*, Aug. 12, 2002, detailed substantially the same kickback activities of Medco as the relator sets forth in his complaint. *See Def. Decl.*, Exh. 16. The article discussed Medco's use of rebates to "line their own pockets instead of to reduce costs to consumers." *Id.* at 1. It discussed how the companies have hidden these payments by calling them "educational grants," "data sales fees," or "health management fees," and how these payments "help the pharmaceutical companies maintain artificially high prices" because "they don't have to factor them into

their best-price calculations." *Id.* at 2-3. The example given to illustrate this scheme involved AZ and the sale of Prilosec and Nexium to Medco. The article discussed claims that the PBMs, and specifically Medco, "insist that they pass along most of the rebate money to the corporate health plans, negotiating lower overall prices than corporations could get on their own." *Id.* at 3. Finally, it is noted that Medco's activities had "attracted the attention of Jim Sheehan, an Assistant United States Attorney for the Eastern District of Pennsylvania who has been conducting a wide-ranging inquiry into PBM practices for the past four years." *Id.*

Another article, appearing in the PHILADELPHIA INQUIRER, *A System to Save on Drugs Falters,* February 10, 2003, reported that Medco's response to client concerns about its rebate agreements with drug companies was to share a portion of the rebates with them. *See Def. Decl.*, Exh. 12, p. 3. Not all clients shared in the rebates and this caused some to seek an accounting of Medco's rebates. Medco executive, David Machlowitz's explanation for refusing some clients' requests for an accounting of Medco's rebates was: "If it is not a part of our deal with them, and they're getting what the contracted for, and its not something we've done on their behalf, why would they be auditing that?" *Id.* From this article the reader (or the government) could conclude that some clients of Medco (perhaps those trophy accounts) had negotiated deals to share in Medco's rebates and incentives. It would not be unreasonable to further conclude that not all clients would have the same bargaining power with Medco as its trophy accounts. These facts are

interesting and may provide additional motive for AZ's actions, but they do not change the underlying fraud alleged by the relator – that AZ gave special deals to Medco that caused it to promote Prilosec and Nexium over less expensive drugs in a manner that disguised the discounted price. As a result, AZ filed false or fraudulent reports and avoided offering these drugs at the best price, in violation of the FCA.

These public disclosures describe schemes designed to hide additional payments made to Medco for the purpose of reducing the cost of Prilosec and Nexium for Medco clients without actually lowering the price AZ reported Medco paid for these drugs. Through this subterfuge, AZ was able to avoid offering these drugs at the same, lower price to the government. It is the failure to report the actual price paid that was in violation of the FCA. This is the essence of the claims raised by the relator, and thus, I find the disclosures were substantially similar to the relator's allegations and sufficient to put the government on notice of the fraud alleged in this action.

2. Best Price Claims Against AZ[11]

The essential elements of the best price fraud are that AZ concealed the true nature of sham rebates to Medco so that AZ would avoid accounting for these sham rebates in its best price reports to the government. These false best price reports are alleged to have caused overstated claims for reimbursement of Medicaid and 340B expenditures to be submitted to the government.

[11] The relator did not assert a claim against AZ under 31 U.S.C. § 3729(a)(7) based on AZ's best price reporting obligations until the third amended complaint was filed on June 15, 2009.

I previously held that the best price claims against the BMS defendants were publicly disclosed before the relator filed this complaint. A review of those same cases reveals that they also specifically implicate AZ's sales of Prilosec and Nexium to Medco.[12] As I found with regard to the BMS defendants:

> These examples demonstrate that the relator's best price claims were also the subject of repeated prior disclosures. The essential elements of the best price fraud – that [AZ] concealed the true nature of the sham rebate and data purchase agreements with Medco (misrepresented facts) so that [AZ] could avoid accounting for those same contracts in its best price reports to the government (true facts) – had already been alleged in numerous other civil actions and were sufficient to set the government on the trail of fraud before the relator filed a complaint with these claims.

See Schumann, 2010 U.S. Dist. LEXIS 109519, at *20-21. The filing of false best price reports resulted in the government paying more for these drugs than permitted by law. This same reasoning applies to establish that the essential elements of the relator's best price fraud claims against AZ were publicly disclosed.

3. Public-Disclosure Bar Applies

I find the relator's allegations are not fundamentally different than the publicly disclosed allegations against AZ, but instead are substantially similar. Moreover, the public disclosures were sufficient to put the government on the trail of this fraud and any

[12] I refer specifically to *Jones v. Merck-Medco Managed Care, LLC*, No. 02-0707(D. Nev. July 2, 2002) (First Am. Compl. ¶¶ 7, 40); *City of New York v. Abbott Labs, Inc.*, No. 04-6054 (S.D.N.Y. Aug. 4, 2004) (Compl. ¶¶ 109, 114, 506, and 528); *Montana v. Abbott Labs, Inc.*., No. 02-09-H-DWM (D. Mont. Aug. 1, 2003) (Compl. ¶ 612). AZ cites additional cases in support of this claim in its memorandum.

investigation would lead to Highmark and United, or any other clients of Medco that participated in the scheme. The public disclosure bar therefore applies to the relator's claims.

B. Original Source: Direct and Independent Knowledge

Where the public disclosure bar applies, a relator must establish that he had direct and independent knowledge of the fraud to pursue his claim. In my earlier decision, I found that the relator satisfied Federal Rules of Civil Procedure 8(a) and 9(b) because he sufficiently pleaded the "how, when, and why the fraudulent agreements [between AZ and Medco] were created." 2010 U.S. Dist. LEXIS 109519, at *29. I was careful, however, to distinguish between pleading the circumstances of the fraud itself from pleading direct and independent knowledge. *See id.* at *32. As with his FCA claims against BMS, in this regard the relator falls short.

The Third Circuit has "interpreted direct to mean 'marked by absence of an intervening agency, instrumentality, or influence: immediate.'" *Paranich*, 396 F.3d at 335. The Court has clarified that direct knowledge "must have arisen from [relator's] 'own efforts, . . . not by the labors of others, and . . . [must not be] derivative of the information of others.'" *United States ex rel. Feldstein v. Organon. Inc.*, 364 Fed. Appx. 738, 743 (3d Cir. 2010) (finding relator was not an original source because he did not personally witness or participate in the alleged fraud, but acquired knowledge from emails and conversations with other employees); *see also United States ex rel. Man Tai Lam v. Man*

Tai Lam, 287 Fed. Appx. 396, 400 (5th Cir. 2008) ("Relators found to have direct and independent knowledge are those who actually viewed source documents or viewed first hand the fraudulent activity that is the basis for their qui tam suit. . . . In contrast, when a relator's claim is based on knowledge received from other persons it is not direct and independent.").

The relator argues that information learned in the course of his employment constitutes direct knowledge. *Relator's Sur-Reply*, 7 (citing *United States ex rel. Gonzalez v. Planned Parenthood of Los Angeles*, No. 09-55010, 2010 U.S. App. LEXIS 13523 (9th Cir. 2010)). It is not enough, however, that the relator learn the information via his employment, but he must do so without deriving that information from others.

Just as with the relator's allegations against BMS, he has not alleged "how, when, where, or from whom he obtained the knowledge that the discounts given to Medco were somehow linked to the evasion of [AZ's] best reporting obligations." Relator does not describe how he obtained direct knowledge of the ultimate fraudulent conduct, but instead generally recounts contract negotiations and other meetings in which he participated.

The relator notes that he discussed rebates with the AZ defendants, reviewed contracts discussing the history of the course of dealing between Medco and AZ, and that he was involved in meetings and discussions regarding contracts and other arrangements between Medco and the AZ defendants in connection with Prilosec and Nexium. *Fourth Am. Comp.* ¶ 123. The specifics of the how, when, where or from whom he obtained

knowledge of AZ's dealings with Medco are as follows:

- He discussed "formulary placement, rebates . . . and disease-management agreements" with the AZ defendants. *Id*.

- He reviewed contracts and internal Medco documents discussing the history of the course of dealing between Medco and AZ. *Id*.

- He was "involved in meetings and discussions regarding contracts and other arrangements between Medco and the AZ defendants in connection with . . . Prilosec and . . . Nexium." *Id*.

- On June 28, 2000, he "attended a presentation by [AZ] personnel at which they discussed the addition of Nexium to the Medco PPF and amending the Rebate Agreement." *Id*. ¶ 124

- On February 28, 2001, he "participated in negotiations" and discussed "the amendment to the 1999 Rebate Agreement to add Nexium and to continue paying Prilosec rebates even after patent expiration;" and "how to structure the rebate agreement to incentivize Medco's 'high control' plan customers to add Nexium by paying them up front for discounts through 'Cost Equilization' and other 'special deals.'" *Id*.

- He attended meetings with Mark Mallon, AZ's "chief negotiator for the amendment." *Id*.

- He had "regular discussions with [AZ] employees . . . to discuss the progress in getting specific managed care plans' addition to Nexium to their formularies in exchange for Cost Equilization deals . . . by which AZ Defendants would agree to match the price of the lowest net price PPI available." *Id*. ¶ 125.

In my prior decision I concluded that such assertions were insufficient to establish that the relator had direct and independent knowledge of the ultimate fraud, kickbacks and the use of sham prices to obtain overpayments from the government. 2010 U.S. Dist. LEXIS 109519, at *23. Again, "I am left to guess how he obtained knowledge of fraud."

Id. I conclude the same with regard to the relator's claims against AZ.[13]

C. Conclusion

The relator's kickback and best price claims fail to overcome the FCA's public-disclosure bar. The claims against AZ are substantially similar to allegations already disclosed and the relator has failed to establish that he is an original source because he has not alleged direct and independent knowledge of the alleged fraud. Accordingly, I must dismiss the relator's claims against AZ pursuant to Rule 12(b)(1) for lack of jurisdiction. I dismiss these claims with prejudice because the relator has had sufficient opportunity to cure these deficiencies and I find that any further amendment would be futile. Having dismissed all the federal claims against defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP, I decline to exercise supplemental jurisdiction over the state law claims.

An appropriate order follows.

[13] Having found that the relator is not an original source, there is no need to consider whether he properly disclosed his claims prior to initiating this action.